

REMARKS

Claims 1-9 and 14-16 are pending and under examination in the present application. No claims are amended or added in the instant paper. Accordingly, claims 1-9 and 14-16 remain pending and under consideration.

Applicant notes with appreciation the withdrawal of the written description rejection under 35 U.S.C. § 112, first paragraph, and kindly thank the PTO for the same.

I. THE OBVIOUSNESS REJECTION SHOULD BE WITHDRAWN

Claims 1-9 and 14-16 stand rejected as allegedly obvious over Lachman *et al.* ("Lachman") in combination with US Patent No. 5,955,102 (the "102 patent") and US Patent No. 5,817,323¹ (the "323 patent"). Applicant respectfully requests reconsideration and withdrawal of the rejection in light of the arguments that follow.

In particular, Applicant respectfully submits that the cited references, whether considered separately or in combination, fail to render the instant claims *prima facie* obvious. Specifically, none of the references, whether considered alone or in combination, teaches or suggests a gelatin capsule that comprises, *inter alia*, a **water-soluble flavoring** that is present in the range of **between about 0.1% and 1.5%**. Further, Applicant has provided evidence sufficient to demonstrate the nonobviousness of the present claims by showing 1) the surprisingly narrow range of flavoring concentrations that result in an acceptable flavor; 2) the commercial success of a product embodying Applicant's invention; and 3) the expert opinion of one skilled in the art indicating that a product embodying Applicant's invention satisfied a long-felt need. Accordingly, Applicant respectfully submits that the present claims are not obvious.

A. The Legal Standard

The Supreme Court's decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966) sets forth the controlling standard for assessing purported obviousness of a claimed invention: "[T]he scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined." *See id.* at 17-18.

¹ Applicant notes that the previous Office Actions and Responses in connection with this application have referenced US Patent No. 5,718,323. Applicant believes that the correct number for this patent is as set forth above and respectfully request that the PTO clarify the record.

The Supreme Court's decision in *KSR. Int'l Co. v. Teleflex*, 127 S.Ct. 1727, (2007) provides guidance regarding exactly how the differences between the prior art and claimed invention are analyzed to assess the obviousness or non-obviousness of the claims. As the Supreme Court explained, "interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art" can all be assessed "to determine whether there was an apparent reason to combine the known elements" as recited by the claim at issue. *See id* at 1731.

Moreover, the law remains clear post-*KSR* that even a *prima facie* case of obviousness can be rebutted. Where the combination of claim elements "worked together in an unexpected and fruitful manner," the claimed invention is likely to be nonobvious. *See KSR* at 1740. Thus, *KSR* confirms that even if an invention might be considered *prima facie* obvious, any conclusion of obviousness may be rebutted by a showing of surprising or unexpected advantageous properties. *See KSR* at 1739; *see also In re Papesch*, 137 USPQ 43 (CCPA 1963), *In re Wiechert*, 152 USPQ 247 (CCPA 1967), *In re Chupp*, 2 USPQ2d 1437 (Fed.Cir. 1987). Further, the Federal Circuit has confirmed that unexpected or surprising advantageous properties may be used to show non-obviousness under the *KSR* framework. *See Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2d 1196 (Fed.Cir. 2008). The showing of such advantageous properties should be commensurate in scope with the claims or allow one of ordinary skill in the art to ascertain a trend that suggests a reasonable extension of the showing to the full scope of the claimed subject matter. *See In re Clemens*, 206 USPQ 289 (CCPA 1980).

Further, secondary considerations may be used to rebut a showing of alleged *prima facie* obviousness. *See KSR* at 1739, *Graham* at 17. Among such secondary considerations are commercial success of a product embodying the claimed invention and a long felt but unsolved need for a product embodying the claimed invention. *See KSR* at 1730.

Finally, a *prima facie* case of obviousness "can be rebutted if the applicant . . . can show 'that the art in any material respect taught away' from the claimed invention." *In re Geisler*, 116 F. 3d 1465, 1469 (Fed. Cir. 1997), quoting *In re Malagari*, 499 F. 2d 1297, 1303 (CCPA 1974). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference . . . would be led in a direction divergent from the path that was taken by the applicant." *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F.3d 1353, 1360 (Fed. Cir.

1999). It is improper to combine references where the references teach away from their combination. *See In re Grasselli*, 713 F.2d 731 (Fed. Cir. 1983).

B. The Cited References Do Not Establish *Prima Facie* Obviousness of the Claims

The combination of references cited by the PTO fail to render the claimed invention *prima facie* obvious because the references, whether considered alone or in combination, fail to teach or suggest a gelatin capsule suitable for administration of fish oil where the capsule comprises a **water soluble flavoring** that is present in the range of **between about 0.1% and 1.0%**. Moreover, the cited combination of references fails to identify any reason why the teaching of the prior art should be modified to obtain the capsules as presently claimed. Accordingly, the claimed invention is not obvious.

Lachman discloses a gelatin capsule that comprises either ethyl vanillin at 0.1% or essential oils at a concentration of up to 2%. Neither ethyl vanillin nor essential oils are water-soluble.² Accordingly, Lachman does not teach anything regarding use of a water-soluble flavoring in connection with any gelatin capsule, let alone provide any suggestion of water-soluble flavoring concentrations suitable for use in a capsule for administering fish oil.

The '323 patent teaches gelatin capsules that comprise, *inter alia*, flavorings including "essential oils, such as lemon, orange, and peppermint oils, fruit flavours, aniseed, liquorice, caramel, honey, cream, various spices, and combination of these and other flavours." *See* the '323 patent, col. 5, lines 45-49. As discussed above, essential oils are not water-soluble flavorings. As such, this portion of the '323 patent's teaching regarding use of flavorings adds nothing beyond the teaching of Lachman.

With respect to the "fruit flavours" of the '323 patent, it is unclear whether these flavors are water-soluble or not; nonetheless, whether or not the fruit flavors of the '323 patent are water-soluble, the '323 patent provides no indication that such flavors should or could be used in a range of between about 0.1% to about 1.5%. Indeed, to the extent the '323 patent discloses concentrations of flavors for use in gelatin capsules, the '323 patent teaches that flavoring should be used in the amounts of about 5% or 6%. *See* the '323 patent,

² Applicant notes that the PTO characterized Applicant's discussion of Lachman in the response filed May 19, 2008, as admitting that Lachman discloses a water-soluble flavoring agent. Applicant respectfully disagrees; Applicant argued that *whether or not* Lachman disclosed a water-soluble flavoring agent, the claims were patentable over Lachman. Applicant has reconsidered and now argue on the basis that Lachman does not disclose any water-soluble flavorings.

Examples C1-C10 at col. 6, line 1 to col. 7, line 18. Thus, the '323 patent actually teaches away from use of the surprisingly low concentration of water-soluble flavoring discovered by Applicant, further demonstrating the nonobviousness of the claimed subject matter..

The '102 patent, as acknowledged by the PTO, does not disclose any flavoring of gelatin capsules, whether water-soluble or otherwise.

Accordingly, the cited combination of references, whether considered alone or in combination, fails to teach or suggest each and every element of the invention as presently claimed. The PTO has identified no reason from the combination of references why one of ordinary skill in the art would be specifically motivated to reduce the amount of flavoring disclosed by the '323 patent or use water-soluble flavorings instead of those disclosed by Lachman. Only hindsight guided by Applicant's disclosure guides the modification of the disclosure of the prior art to the selection of these particular elements recited by the instant claims, in direct contravention of binding precedent. ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *See KSR* at 1742). As such, the PTO cannot establish *prima facie* obviousness of the present claims.

Moreover, Applicant has provided extensive evidence of unexpected results, commercial success, and long-felt need for Applicant's invention. In particular, the Declaration of Joar Opheim dated December 7, 2005 (the "First Opheim Declaration"), establishes that a surprisingly narrow range of water-soluble flavorings of between about 0.25% and about 1.5% resulted in acceptable taste. These results are nearly co-extensive with the range recited by the instant claims and are surely sufficient to allow one skilled in the art to ascertain a trend extending to the full scope of the claimed range.

The PTO argues that the evidence of unexpected results should include data from outside the claimed range to show comparative results with those achieved within the claimed range. Applicant respectfully disagrees that such evidence is required to demonstrate the unexpected nature of the claimed invention. Rather, all that is required is to show the surprising property is commensurate in scope with the claimed subject matter or would allow one of ordinary skill in the art to ascertain a trend showing such commensurate scope. Applicant believes that the First Opheim Declaration does show such a trend.

With respect to the PTO's objection that the First Opheim Declaration discloses results from a single water-soluble flavor, Applicant again believes that the results are

sufficient for one of ordinary skill in the art to ascertain a trend demonstrating the surprising nature of the entire scope of the claimed subject matter. Applicant further notes that Applicant has provided further evidence, herewith, that a second water-soluble flavor, lemon flavor, is palatable within the claimed range.

With respect to the PTO's objection to the showing of commercial success provided in the Declaration of Joar Opheim dated September 21, 2006, (the "Second Opheim Declaration"), Applicant submits herewith another Declaration of Joar Opheim (the "Third Opheim Declaration") the providing evidence that the flavored capsules referenced by the Second Opheim Declaration are embodiments of the present invention. *See* the Third Opheim Declaration, ¶2. As such, the sales data provided in the Second Opheim Declaration is potent evidence that the water-soluble flavoring of the capsules results in great commercial success, further demonstrating the nonobviousness of the claimed invention.

Further, Applicant respectfully invites the PTO's attention to the Declaration of Oliver Cooperman, M.D. (the "Cooperman Declaration"), dated March 29, 2007. In the Declaration, Dr. Cooperman provides his opinion that the ProEPA and ProOmega capsules satisfy a long-felt need for a more palatable fish oil product and attributes the increase in palatability to the water-soluble flavoring added to the gelatin capsules. *See* the Cooperman Declaration, ¶ 6. The Third Opheim Declaration makes clear that these products are also embodiments of the present invention. *See* the Third Opheim Declaration, ¶3. As such, Applicant has further provided evidence that embodiments of the invention as presently claimed satisfy a long-felt but unmet need, further demonstrating the nonobviousness of the claimed subject matter.

Accordingly, Applicant respectfully submits that the PTO has failed to establish *prima facie* obviousness of the claimed subject matter over Lachman in view of the '102 patent and the '323 patent. Further, Applicant has provided evidence of unexpected results, commercial success, and satisfaction of long-felt but unmet needs by embodiments of the present invention. Accordingly, Applicant believes that the obviousness rejection has been overcome and respectfully requests that the PTO reconsider and withdraw the rejection.

II. CONCLUSION

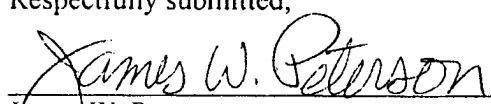
In view of the foregoing, Applicant respectfully submits that the present application is in condition for allowance and earnestly request an early indication of the same. The

Examiner is invited to call the undersigned attorney at (650) 739-3949 if a telephone call could help resolve any remaining items.

No fee is believed due with this response other than the fee for the extension of time for response. However, should the Commissioner determine otherwise, the Commissioner is hereby authorized to charge any required fee(s) to Jones Day Deposit Account No. 50-3013 (Order No. 282019-999012).

Respectfully submitted,

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